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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

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11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/738,599	Applicant(s) Nolan et al.
Examiner S. Devi, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jul 16, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-66 is/are pending in the application.

4a) Of the above, claim(s) 1-29, 35, 36, and 46-66 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 30-34 and 37-45 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6.

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Preliminary Amendment

1) Acknowledgment is made of Applicants' preliminary amendment filed 01/15/02 (paper no. 7). With this, Applicants have amended the specification.

Sequence Listing

2) Acknowledgment is made of Applicants' submission of CRF/sequence listing which has been entered on 10/18/01 (paper no. 5).

Election

3) Acknowledgment is made of Applicants' election, with traverse (filed 07/16/02 - paper no. 9) of invention III, claims 30-34 and 37-45, in response to the restriction requirement mailed 06/25/02 (paper no. 8). Applicants' traversal is on the grounds that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner.

Applicants' argument has been carefully considered, but is not persuasive. As clearly set forth in the restriction requirement mailed 06/25/02, the various inventions are drawn to distinct methods, that differ from one another in method steps/parameters, reagents used, and/or ultimate goals accomplished. Furthermore, as set forth in the restriction requirement mailed 06/25/02, MPEP 806.05(h) and MPEP 806.05(f) permit restriction of a product from methods of using or making the product. The inventions belong to distinct classes and/or subclasses thus requiring non-coextensive burdensome searches. For these reasons, the restriction requirement filed 06/25/02 is proper and is hereby made FINAL.

Status of Claims

4) Claims 1-66 are pending.

Claims 1-29, 35, 36 and 46-66 have been withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 30-34 and 37-45 are under examination. An Action on the Merits for these claims is issued.

Priority

5) The instant application is a continuation-in-part of the application SN 09/282,352, filed

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03/31/99, now US patent 6,187,321, which is a Divisional application of SN 09/023,221, filed 02/12/98, now US patent 6,087,128.

Specification - Informalities

6) The instant specification is objected to for the following reason(s):

- (a) The first paragraph of the specification does not accurately reflect the current issued status of the earlier filed application(s) as indicated above in italicized letters under 'Priority'. Amendment to the first paragraph of the specification is needed to reflect this.
- (b) The use of the trademarks in the instant specification has been noted in this application. For example, see page 57, lines 2 and 9: "Sepharose 4B"; page 61, line 20 and page 69, line 1: "Amplitaq"; and page 44, last line: "Squalene/Tween 80". Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to the trademarks, wherever trademark recitations appear.
- (c) The instant specification incorporates subject matter into the patent application by reference to hyperlinks. For example, see line 12 on page 11 and line 13 on page 13. However, attempts to incorporate subject matter into the patent application by reference to active hyperlinks and/or other forms of browser-executable code are considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I. Such embedded active hyperlinks and/or other forms of browser-executable code therefore require deletion. It is suggested that Applicants examine the whole specification to make similar deletions of hyperlinks, wherever such hyperlink recitations appear.
- (d) On page 42, line 1, the address of the American Type Culture Collection is incorrect. Effective 23 March 1998, ATCC has a new address: 10801 University Boulevard, Manassas, VA 20110-2209. Amendment to the specification is suggested to reflect this. It is suggested that Applicants examine the whole specification to make similar correction to the address, wherever it appears.

Double Patenting Rejection(s)

7) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

Instant claims 37-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of the U.S. Patent 6,087,128. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the overlapping scope.

Instant claims 30-34, 43 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of the U.S. Patent 6,087,128. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the overlapping scope.

Rejection(s) under 35 U.S.C § 101

8) Claim 37 is rejected under 35 U.S.C § 101 as being directed to a non-statutory subject matter. The claim encompasses an immunogenic composition comprising a non-isolated nucleic acid molecule encoding an avian *E. coli* Iss polypeptide, an immunogenic fragment or subunit thereof, and therefore reads on products of nature, i.e., naturally occurring avian *E. coli* isolate. The claim lacks limitations which distinguish this product from those that may exist naturally.

Consequently, the claim does not embody patentable subject matter as defined in 35 U.S.C § 101. See MPEP 2105. The rejection can be obviated by amending claim 37 to recite --An immunogenic comprising an isolated nucleic acid molecule-- in connection with the product to reflect the hands of the inventors in the production or creation of the recited product if such a recitation has descriptive support in the specification, as originally filed.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

9) Claims 30-34 and 37-45 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 30 is vague in the recitation “73 to 309 of SEQ ID NO: 22” without reciting that SEQ ID NO: 22 is a nucleotide sequence. In order to distinctly claim the subject matter of the instant invention, it is suggested that Applicants replace the recitation with --73 to 309 of the nucleotide sequence, SEQ ID NO: 22--.

(b) Analogous criticism applies to claims 31, 33, 34, 43, 44 and 45.

(c) Claim 32 includes improper antecedent basis for the recitation: “the nucleic acid sequence”. Claim 32 depends from claim 30, which does not include the recitation: “nucleic acid sequence”.

(d) Claim 33 is vague, incorrect and/or confusing in the recitation “to a least one” (see line 2).

(e) Claim 34 is vague and indefinite in the recitation “under stringent conditions”.

What conditions qualify as ‘stringent conditions’? Does this limitation encompass low, medium and high stringency conditions?

(f) Claims 37 and 43 are vague and indefinite in the recitation “subunit” of an avian *E. coli* Iss polypeptide, because it is not clear what is encompassed in the term “subunit”. It is unclear which at least 7 to 14 amino acids-containing part of the polypeptide is encompassed in this subunit, or what part of the polypeptide constitutes a subunit.

(g) Claim 42 is vague and indefinite in the recitation “immunostimulatory sequence”, because it is unclear what does the ‘immunostimulatory sequence’ represent. Is this ‘sequence’ a nucleotide sequence or an amino acid sequence?

(h) Claim 43 is vague and indefinite in the recitation: “fragment thereof”, because it is unclear what is encompassed in this limitation, or what constitutes a ‘fragment’. Does a single amino acid residue constitute a ‘fragment thereof’?

(i) The recitation “fragment thereof” in claim 43 is improperly broadening in scope. Claim 43 depends from claim 38 which includes the much narrower limitation “immunogenic fragment”.

(j) Claims 38-45, which depend directly or indirectly from claim 37, are also rejected as being indefinite, because of the vagueness or indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

10) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11) Claims 30 and 34 are rejected under 35 U.S.C § 102(a) as being anticipated by GenEmbl Accession AF042279, GI:5305230, submitted 01/10/1998 (Horne, Nolan, Giddings and Pfaff).

A sequence search performed in the Office revealed that the nucleotide sequence having GenEmbl Accession AF042279, GI:5305230, has 100% identity with the instantly claimed nucleic acid molecule comprising nucleotides 73 to 309 of the nucleotide sequence, SEQ ID NO: 22. See the attached sequence report. Due to the perfect 100% sequence identity, it is inherent that the prior art nucleotide sequence would hybridize with the claimed nucleic acid molecule claimed in claim 34 under stringent conditions. The prior art sequence is stated as being the gene for a protein that is similar to Iss protein from a septicemic human *E. coli* isolate. Claims 30 and 34 are anticipated by GenEmbl Accession AF042279, GI:5305230.

12) Claims 34, 37-40 and 43 are rejected under 35 U.S.C § 102(b) as being anticipated by Barondess *et al.* (*Nature* 344: 871-874, 1990 - Applicants' IDS) (Barondess, 1990), or Chuba *et al.* (*Mol. Gen. Genet.* 216: 287-292, 1989 - Applicants' IDS).

A “subunit” is defined on page 10 of the specification as a biologically active portion,

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region or peptide of a full-length Iss polypeptide. A subunit of an *E. coli* Iss derived polypeptide is described as preferably having at least 7 amino acids, more preferably at least 10 amino acids, most preferably at least 14 amino acids.

Chuba *et al.* or Barondess *et al.* (1990) disclose a nucleic acid molecule comprising several stretches of at least 13 nucleotides (i.e., fragments or subunits) showing 100% sequence identity with nucleotides 73 to 309 of SEQ ID NO: 22, plasmids, vectors, phages and host cells comprising the same. See the attached sequence search reports and the entire reference. That the prior art nucleic acid molecule hybridizes to nucleotides 73 to 309 of SEQ ID NO: 22 under stringent conditions that are unspecified in the instant claim(s) is inherent from the teachings of Chuba *et al.* or Barondess *et al.* (1990). That the prior art nucleic acid serves intrinsically as an immunogenic composition is inherent from the teachings of Chuba *et al.* or Barondess *et al.* (1990). The immunogenic function is viewed as an inherent property of the prior art nucleic acid molecule which meets the structural elements of the claimed product.

Claims 34, 37-40 and 43 are anticipated by Chuba *et al.* or Barondess *et al.* (1990).

Remarks

- 13) Claims 30-34 and 37-45 stand rejected.
- 14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242 which receives papers 24 hours a day, seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.
- 15) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached Monday through Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's

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supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September, 2002


S. DEVI, PH.D.
PRIMARY EXAMINER